State Fiscal Year 2001

Annual Report of the Department of Rehabilitative Services Human Research Review Committee

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Commissioner

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Authority and Duties of the Committee

Section 51.5-5.1 of the Code of Virginia requires the Department of Rehabilitative Services (DRS) Human Research Review Committee (HRRC) to submit to the Governor, the General Assembly, and the DRS Commissioner at least annually a report on the human research projects reviewed and approved by the committee, including any significant deviations from the proposals as approved. This report presents State Fiscal Year 2001 activities of the DRS HRRC.

The HRRC has internal oversight responsibilities for ensuring protection of the rights and welfare of DRS clients who volunteer to participate in research conducted or authorized by the department or any of its entities covered by the Code. The regulation gives the entities the options to: 1) establish their own research review committee, 2) work with other institutions to establish a single committee, or 3) use the DRS established committee. A list of the 96 entities which are either part of DRS or partner with DRS is provided at Appendix A (1 Rehabilitation Center, 1 university based rehabilitation research and training center, 16 Centers for Independent Living, and 78 Employment Services Organizations). To carry out its oversight responsibilities, the committee reviews and approves applications for proposed research. The committee follows regulatory procedures as specified by 22 VAC 30-40-10 et seq. and applicable federal regulations concerning human subject research. The primary federal regulatory body is the Department of Health and Human Services (the Food and Drug Administration, The National Institutes of Health, and the Office of Human Research Protections).

To supplement regulatory requirements, the committee has a procedures manual which standardizes committee practices and activities, describes study participant complaint procedures, specifies the responsibilities of investigators, and provides templates for: 1) investigator application, 2) voluntary informed consent, and 3) investigator periodic progress report. The DRS Commissioner established the committee in August 2000 to review and approve all research to be conducted or authorized by DRS or the Woodrow Wilson Rehabilitation Center

(WWRC), as well as the Centers for Independent Living (CILs) and facility-based community rehabilitation programs in Virginia. Elizabeth E. Smith, DRS Policy and Planning Director is the committee's chair and this is the committee's first annual report. The composition of the committee is governed by 22 VAC 30-40-60 and a list of committee members is provided at Appendix B.

The committee meets monthly or as needed to fulfill its responsibilities and must meet at least once annually. A quorum of the committee consists of a majority of its members including at least one member whose primary concerns are in nonscientific areas. The committee's responsibilities begin when a research proposal is submitted to the chair for review and approval. Upon receipt of an application, the committee chair determines whether the proposal merits exempt review, expedited review, or will undergo full committee review. Elements of the committee's review include consideration to potential benefits and risks and the methodology of the research, the degree of risk for nontherapeutic research, the protection of the rights and welfare of participants, voluntary informed consent, competency of the research investigators, equitable selection criteria for research participants, adherence to other criteria as established by the Board for Rehabilitative Services, and whether appropriate studies in nonhuman systems have been conducted prior to the involvement of human participants. All research proposals are reviewed within 45 days of submission of a completed application to the chair. Research investigators are notified in writing of the committee's decision to approve or disapprove the proposed research activity, or of modifications required to secure approval.

Overview of Reviewed and Approved Research

There were a total of nine studies reviewed and approved by the HRRC during State Fiscal Year 2001. Four studies were approved by "exempt review", two studies were approved by "expedited review" and three studies were approved by "full committee review". A list of research proposals reviewed and approved by the committee is at Appendix C. The three types of review are

explained at Appendix D. The committee has no evidence suggesting that there were any significant deviations from proposals as approved.

Overview of DRS

DRS is committed to increasing high-quality employment outcomes for people with disabilities by providing effective services and by working with employment and training programs, service providers, and employers to achieve the employment and independence of people with disabilities. DRS operates the federally-funded Vocational Rehabilitation (VR) program that provides individuals with disabilities with a comprehensive array of services to enable them to obtain, retain, or advance in employment. These services include vocational evaluation, job placement, career counseling, vocational and academic training, rehabilitation technology, physical restoration, and personal assistance service. DRS operates the Woodrow Wilson Rehabilitation Center (WWRC) which provides comprehensive services to people with physical, mental, sensory, and emotional disabilities. WWRC consumers participate in residential or outpatient programs ranging from early medical rehabilitation to complete vocational services and re-entry to the community. In addition to its agency programs, the Department has strong partnerships with many community-based rehabilitation providers across the Commonwealth. For example, DRS purchases facility-based employment and supported employment services from Employment Services Organizations (ESOs), the Community Rehabilitation Providers in Virginia. Using a combination of federal and state dollars, DRS provides extended employment, situational assessment, supported employment, and work adjustment training through the ESOs. DRS also works closely with private, non-profit Centers for Independent Living (CILs), which provide independent living skills, training, advocacy, information and referral, and peer counseling for individuals with disabilities, as well as with community organizations and state agencies involved with education and training for people with disabilities.

Appendix A: Covered entities and their HRRC affiliation

Agencies/Organizations	Type Agency / Organization[1]	HRRC Used to Review Proposed Research[2]	Does Not Authorize or Conduct Research[3]
Access Independence, Inc.	CIL	DRS	
Appalachian Independence Center	CIL	DRS	
Blue Ridge Independent Living Center	CIL	DRS	
Central Virginia Independent Living Center	CIL	DRS	
Clinch Independent Living Services	CIL	DRS	
DisAbility Resource Center	CIL	DRS	
Eastern Shore Center for Independent Living	CIL	DRS	
Endependence Center of Northern Virginia	CIL	DRS	
Endependence Center, Inc.	CIL	DRS	
Independence Empowerment Center, Inc.	CIL	DRS	
Independence Resource Center	CIL	DRS	
Junction Center for Independent Living	CIL	DRS	
Lynchburg Area Center for Independent Living	CIL	DRS	
Peninsula Center for Independent Living	CIL	DRS	
Piedmont Independent Living Center	CIL	DRS	
Valley Associates for Independent Living, Inc.	CIL/ESO	DRS	
City of Virginia Beach, Community Services Board Mental Retardation Programs Employment Services Unit	CSB	DMHMRSAS[4]	
Highlands Community Services Board	CSB	DRS	
Alexandria Community Services Board	CSB/ESO	Established its Own Committee	
Chesterfield Employment Services	CSB/ESO	DRS	
Colonial Services Board (formerly known as Colonial Workshop, Inc.)	CSB/ESO		X
County of Prince William Community Services Board	CSB/ESO	DRS	
Crossroads Community Services Board	CSB/ESO	DRS	
Department of Behavioral Healthcare Services (The City of Portsmouth)	CSB/ESO		X
Eastern Shore Community Service Board	CSB/ESO		X

Agencies/Organizations	Type Agency / Organization[1]	HRRC Used to Review Proposed Research[2]	Does Not Authorize or Conduct Research[3]
Goodwill Industries of Hampton Roads, Inc.	CSB/ESO	DRS	
Hampton/Newport News Community Services Board	CSB/ESO	DRS	
Henrico Area Mental Health & Retardation Services	CSB/ESO		X
Loudoun County Community Services Board	CSB/ESO		X
Mt. Rogers Industrial Developmental Center	CSB/ESO	Established its Own Committee	
Region Ten Community Services Board, Blue Ridge House	CSB/ESO	DRS	
Rockbridge Area Community Services Board	CSB/ESO	DRS	
The Job Avenue (part of the Arlington Community Services Board)	CSB/ESO	DRS	
Valley Community Services Board	CSB/ESO	DRS	
Woodrow Wilson Rehabilitation Center (WWRC)	DRS Rehabilitation Center	DRS	
Adult Activity Services	ESO	DRS	
ASPIRE, Inc.	ESO	DRS	
Career Support Systems	ESO	DRS	
Chesapeake Vocational Center, Inc.	ESO	DRS	
Colonial MH & MR Services	ESO	DRS	
Commonwealth Support Systems	ESO		X
Community Alternative, Inc.	ESO		X
Danville ARC, Hatcher Center	ESO	DRS	
Davis Memorial Goodwill Industries	ESO		X
Didlake, Inc.	ESO	DRS	
Elevare, Inc.	ESO	DRS	
Every Citizen Has Opportunities	ESO		X
Friendship Industries, Inc.	ESO	DRS	
Frontier Health	ESO	DRS	
Goochland-Powhatan Community Services	ESO	DRS	
Goodwill Industries of Danville Area, Inc.	ESO	DRS	
Goodwill Industries of Tenneva Area, Inc.	ESO	DRS	

Agencies/Organizations	Type Agency / Organization[1]	HRRC Used to Review Proposed Research[2]	Does Not Authorize or Conduct Research[3]
Goodwill Industries of the Valleys Central Division	ESO	DRS	
Goodwill Industries of the Valleys Western Division	ESO	DRS	
Hanover County Community Services Board	ESO	DRS	
Hired Hands & Associates	ESO	DRS	
ICON Community Services, Inc.	ESO	DRS	
Jackson River Enterprises, Inc.	ESO	DRS	
Job Discovery, Inc.	ESO	DRS	
Lewis B. Puller Center, Inc	ESO	DRS	
Longwood Industries, Inc.	ESO		X
Louise W. Eggleston Center	ESO		X
Lynchburg Sheltered Industries	ESO	DRS	
MARC Workshop	ESO	DRS	
Mount Vernon Lee Enterprises	ESO	DRS	
Northwestern Workshop, Inc.	ESO	DRS	
OPCO/St. Johns' Community Services	ESO	DRS	
Open Door, Inc.	ESO	Established its Own Committee	
PARC Services	ESO	DRS	
PARC Workshop, Inc.	ESO	DRS	
Pleasant View	ESO	Established its Own Committee	
Psychiatric Rehabilitation Services, Inc.	ESO	DRS	
Rappahannock Goodwill Industries, Inc.	ESO		X
Richmond Area ARC	ESO	DRS	
Richmond Goodwill Industries, Inc.	ESO	DRS	
Rockbridge Area Occupational Center, Inc.	ESO	DRS	
RSVP, Inc.	ESO	DRS	
ServiceSource	ESO	DRS	
Shen-Paco Industries	ESO		X
SOC Enterprises	ESO	DRS	
Southside Training Employment Placement Services, Inc.	ESO	DRS	
Sugar Plum, Inc.	ESO	DRS	

Agencies/Organizations	Type Agency / Organization[1]	HRRC Used to Review Proposed Research[2]	Does Not Authorize or Conduct Research[3]
The ARC of the Virginia Peninsula Hudgins Center	ESO	DRS	
The Choice Group	ESO	DRS	
The Danville Association for Retarded Citizens, Inc. (The Hatcher Center)	ESO	DRS	
The Sheltered Workshop of Altavista, Inc.	ESO	DRS	
Thompson's Brain Injury Rehab, Inc.	ESO	DRS	
Tidewater Occupational Center	ESO	DRS	
Valley Employment Services, Inc.	ESO	DRS	
Vector Industries, Inc.	ESO	DRS	
Virginia Support Services, Inc	ESO	DRS	
WAC Industries/W.C. Ham Center	ESO	DRS	
Warren County Workshop, Inc.	ESO	DRS	
WorkSource Enterprises, Inc	ESO	DRS	
Wright Choices Inc.	ESO	DRS	
Rehabilitation Research and Training Center on Workplace Support (Virginia Commonwealth University, VCU)	Research and Training Center	VCU[5]	

Notes:

1. DRS operates Woodrow Wilson Rehabilitation Center (WWRC) which provides comprehensive services to people with physical, mental, sensory, and emotional disabilities. The Department also has partnerships with community-based employment and supported employment services from Employment Services Organization (ESOs) and from ESOs that are part of Community Services Boards (CSBs). The actual number of ESOs that have Federal Identification Numbers (FIN) is greater than the number of ESOs in this table because several ESOs in the above table have administrative authority for all branches within the organization. As an example, Frontier Health is listed in the above table but not its branch ESOs. Branches of Frontier Health include Developmental Services, Independence Unlimited, Opportunities Unlimited-Bristol, and Opportunities Unlimited-Kingsport.

2. HRRC used to review proposed research – 22 VAC 30-40-40 gives each DRS agency/organization the options to 1) establish its own research review committee, 2) work with other institutions to establish a single committee, or 3) use the Department of Rehabilitative Services (DRS) established committee.

3. Some agencies/organizations indicated that their policies prohibit the conduct of research involving their clients. Therefore, these agencies/organizations have decided that they do not need the services of a human research review committee.

4. Department of Mental Health Mental Retardation and Substance Abuse Services (DMHMRSAS)

5. Virginia Commonwealth University (VCU)

Appendix B: Department of Rehabilitative Services Human Research Review Committee Members

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[1] Chair, HRRC

[2] Vice Chair, HRRC

Appendix C: Studies Reviewed and Approved in State Fiscal Year 2001

Study Title	Type of Review	Date approved	Periodic Review Period	DRS Control Number
Case Report: Use of partial body weight supported treadmill training to progress beyond a plateau in functional ambulation for a person with incomplete paraplegia.	exempt	3/21/2001	N/A study used existing data	00001
Investigate how persons with and without brain damage are able to process particles such as "oh" and "well". Use of language comprehension and production tasks.	expedited	4/12/2001	Annual Review, study duration: 32 months	00002
Ethical decision-making in rehabilitation counseling. Purpose is to compare different models of ethical decision-making for rehabilitation counselors working in public rehabilitation settings. Research done through training on ethical decision making models.	exempt	12/19/2000	Annual Review, study duration: 8 weeks	00003
Participation in renorming study of the motor-free visual perception test.	exempt	3/5/2001	Annual Review, study duration: 3 months	00004
Investigate staffing patterns in the state-federal vocational rehabilitation programs of Rehabilitation Counselors for the Deaf (RDCs) via survey questionnaire.	exempt	2/9/2001	N/A study used existing data	00005
Reducing Manual Wheelchair Users' Shoulder Pain in Persons with Spinal Cord Injury.	full	5/22/2001	Annual Review, study duration: 24 months	00006
Improving Community-Based Follow-up Services to Address Long-term Health Maintenance Needs for Persons with Spinal Cord Injury Residing in Southwest Virginia.	full	5/22/2001	Annual Review, study duration: 36 months	00007

Study Title	Type of Review	Date approved	Periodic Review Period	DRS Control Number
Clean Techniques of Bladder Management: Comparison of Cleaning Methods.	full	5/22/2001	Annual Review, study duration: 12+ months	00008
Perceptions of First-Time Participants in an Employer-Sponsored Online Graduate Program and its Implications for Online Education Planning and Support.	expedited	5/1/2001	Annual Review, study duration: 8 weeks	00009

Appendix D: Types of Review

The Committee through its chair determines whether the proposal merits exempt review, expedited review, or undergoes full review.

Research Exempt from Full Review

Unless they are covered by some other provision, the following kinds of research are exempt from full review by the Human Research Review Committee:

1. Research conducted in established or commonly accepted education settings, involving commonly used educational practices, such as:

    a) Research on regular and special education instructional strategies; or

    b) Research on the effectiveness of or the comparison among instructional techniques, curriculum or classroom management methods.

2. Research involving solely the use and analysis of the results of standardized psychological, educational, diagnostic, aptitude, or achievement tests, if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

3. Research involving survey or interview procedures, unless responses are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants; and either:

    a) The participant's responses, if they become known outside the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation; or

    b) The research deals with sensitive aspects of the participants' own behavior, such as sexual behavior, drug or alcohol use, illegal conduct, or family planning.

4. Research involving solely the observation (including observation by participants) of public behavior, unless observations are recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants, and either:

    a) The observations recorded about the individual, if they become known outside the research, could reasonably place the human participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability or reputation; or

    b) The research deals with sensitive aspects of the participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

5. Research involving solely the collection or study of existing data, documents, records, or pathological or diagnostic specimens, if the sources are publicly available, or if the

information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Note: Based on the federal definition of "existing data", research conducted on biological or pathological specimens obtained prospectively and/or taken strictly for research purposes or from future discarded clinical samples DOES NOT qualify for exempt review.

Expedited Review

The Committee may conduct an expedited review of a human research project which involves no more than minimal risk to the participants if

1. If another agency/organization's or agency's human research review Committee has reviewed and approved the project;

2. If the review involves only minor changes in previously approved research and the changes occur during the approved project period; or

3. If research activities involve no more than minimal risk and in which the only involvement of human participants will be one or more of the categories referred to in 34 CFR 97.110 as follows:

   a) Clinical studies of drugs or medical devices for which an investigational new drug application or investigational devise exemption application is not required.

   b) Collection of blood samples that meet NIH guidelines; Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: (a) From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

   c) Collection of biological specimens for research purposes by noninvasive means.

   d) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity,

electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e) Research involving materials that have been collected solely for nonresearch purposes.

f) Collection of data from voice, video, digital, or image recording made for research purposes;

g) Research on individual or group characteristics that is not exempt;

h) Continuing review of research previously approved;

i) Continuing review of research that does not meet the preceding requirements but which had been reviewed by and research Committee that deems that no greater than minimal risk is involved and no additional risks have been identified.

For the expedited review, the Committee chair and one or more experienced reviewers designated by the chair from among members of the Committee may carry out the review. The reviewers may exercise all of the authorities of the Committee except that the reviewers may not disapprove the research. If the expedited review leads to be for disapproval, the proposals would be sent to the full Committee for review.

All Committee members will receive printed notification of the actions of an expedited review.

Full Review

A full review shall include consideration of the following criteria for approval:

1. The adequacy of the description of the potential benefits and risks involved and the adequacy of the methodology of the research;

2. The degree of the risk, and if the research is nontherapeutic, whether it presents greater than minimal risk;

3. Whether the rights and welfare of the participants are adequately protected;

4. Whether the risks to the participants are outweighed by the potential benefits to them;

5. Whether the voluntary informed consent is to be obtained by methods that adequately and appropriately fulfill the requirements of these regulations and whether the written consent form is adequate and appropriate in both content and language for the particular research and for the particular participants of the research;

6. Whether the research investigators proposing to supervise or conduct the particular human research are appropriately competent and qualified;

7. Whether criteria for selection of participants are equitable, especially in research regarding the future development of mental or physical illness;

8. Whether appropriate studies in nonhuman systems if applicable have been conducted prior to the involvement of human participants; and

9. Whether the research conforms with other requirements to be developed.